

What is claimed is:

1. A process for operating a packaging transport system, comprising the steps of:

sterilizing objects packed in at least one layer of packaging which is bacteria-impermeable and gas-permeable;

placing the sterilized objects packed in at least one layer of the at least one layer of packaging into an evacuable sterilization chamber in the form of a transfer lock;

pre-evacuating the sterilization chamber;

applying abruptly a vapor mix consisting of water steam and hydrogen peroxide steam as a condensate layer onto the outer side of the packaging;

re-evacuating the sterilization chamber to remove the condensate layer and the uncondensed vapor mix before either the vapor mix or the condensate layer penetrates through the packaging to the objects at an inadmissible level; and

transferring the sterilized objects and packaging into a sterile clean room.

2. A process for a contamination-free insertion of already sterilized syringes into a filling apparatus surrounded by a sterile clean room for filling and sealing the syringes, comprising the steps of:

providing sterile transport containers containing the syringes with a bacteria-impermeable and gas-permeable cover and a sealed bacteria-impermeable and gas-permeable additional packaging;

releasing the transport containers from their additional packaging;

sterilizing the outer side of the covered transport chambers in an  
evacuatable sterilization chamber which serves as a lock by  
pre-evacuating the sterilization chamber;  
applying abruptly a vapor mix consisting of water steam and hydrogen  
peroxide steam as a condensate layer onto the outer side of the  
covered transport chambers;  
re-evacuating the sterilization chamber to remove the condensate layer  
and the uncondensed vapor mix before either the vapor mix or the  
condensate layer penetrates through the packaging to the objects at  
an inadmissible level; and  
guiding the sterilized transport chambers into the clean room for syringe  
filling in the filling apparatus.

3. A process according to claim 1, wherein a pressure difference  
between a pressure of the vapor mix and a pressure in the evacuated  
sterilization chamber forces the vapor mix to be fed into the sterilization  
chamber without the use of carrier gas.

4. A process according to claim 2, wherein a pressure difference  
between a pressure of the vapor mix and a pressure in the evacuated  
sterilization chamber forces the vapor mix to be fed into the sterilization  
chamber without the use of carrier gas.

5. A process according to claim 1, wherein the speed of the pre-evacuation is adapted to the flow resistance of the gas-permeable cover of the transport container to ensure a gas pressure within the covered transport container remains above a pressure in the sterilization chamber.

6. A process according to claim 2, wherein the speed of the pre-evacuation is adapted to the flow resistance of the gas-permeable cover of the transport container to ensure a gas pressure within the covered transport container remains above a pressure in the sterilization chamber.

7. A process according to claim 1, wherein the condensate layer is removed from the sterilization chamber immediately after the vapor mix has been fed into the sterilization chamber.

8. A process according to claim 7, wherein the removal of the condensate layer by means of evacuation of the sterilization chamber takes place at a pressure below 10 mb.

9. A process according to claim 7, wherein the removal of the condensate layer by means of evacuation of the sterilization chamber takes place at a pressure below 1 mb.

10. A process according to claim 2, wherein the condensate layer is removed from the sterilization chamber immediately after the vapor mix has been fed into the sterilization chamber.

11. A process according to claim 2, wherein the removal of the condensate layer by means of evacuation of the sterilization chamber takes place at a pressure below 10 mb.

12. A process according to claim 2, wherein the removal of the condensate layer by means of evacuation of the sterilization chamber takes place at a pressure below 1 mb.

13. A process according to claim 1, wherein the sterilization chamber is filled with a sterile air after the condensate layer has been removed.

14. A process according to claim 2, wherein the sterilization chamber is filled with a sterile air after the condensate layer has been removed.

15. A process according to claim 1, wherein the condensate layer is applied before an inner pressure of the packaging or the transport container has reached a pressure of the sterilization chamber.

16. A process according to claim 2, wherein the condensate layer is applied before an inner pressure of the packaging or the transport container has reached a pressure of the sterilization chamber.

17. A process according to claim 1, wherein the inadmissible level is a level of hydrogen peroxide residue which exceeds 1.0 ppm.

18. A process according to claim 1, wherein the inadmissible level is a level of hydrogen peroxide residue which exceeds 0.5 ppm.

19. A process according to claim 17, wherein the hydrogen peroxide residue level remains below 0.5 ppm to a great extent.

20. A process according to claim 2, wherein the inadmissible level is a level of hydrogen peroxide residue which exceeds 1.0 ppm.

21. A process according to claim 2, wherein the inadmissible level is a level of hydrogen peroxide residue which exceeds 0.5 ppm.

22. A process according to claim 19, wherein the hydrogen peroxide residue level remains below 0.5 ppm to a great extent.

23. A process according to claim 1, wherein a time span of 14 seconds is provided from the beginning of the flowing in of the vapour mix to the beginning of the re-evacuation.

24. A process according to claims 22, wherein the time span amounts to a maximum of 4 seconds.

25. A process according to claim 23, wherein the time span amounts to a maximum of 2 seconds.

26. A process according to claim 2, wherein a time span of 14 seconds is provided from the beginning of the flowing in of the vapour mix to the beginning of the re-evacuation.

27. A process according to claim 25, wherein the time span amounts to a maximum of 4 seconds.

28. A process according to claim 26, wherein the time span amounts to a maximum of 2 seconds.

29. A process according to claim 2, wherein removal of the additional packaging is not performed if the porosity of the transport container is above a predetermined value.

30. A process according to claim 1, wherein the pre-evacuation, vapor mix application and re-evacuation steps are repeated at least once.

31. A process according to claim 2, wherein the pre-evacuation, vapor mix application and re-evacuation steps are repeated at least once.

32. A process according to claim 29, wherein supporting surfaces of the transport container adapted for use with a holding device or a transport device, and the support surfaces are altered before the pre-evacuation, vapor mix application and re-evacuation steps are repeated.

33. A process according to claim 30, wherein supporting surfaces of the transport container adapted for use with a holding device or a transport device, and the support surfaces are altered before the pre-evacuation, vapor mix application and re-evacuation steps are repeated.

34. A process according to claim 29, wherein during a repeat of the pre-evacuation, vapor mix application and re-evacuation steps, the removal of the condensate layer takes place by evacuation of the sterilization chamber to a pressure level below a steam pressure of water corresponding to a temperature in the sterilization chamber during sterilization.

35. A process according to claim 33, wherein the removal of the condensate layer takes place at a pressure below the steam pressure of a water and hydrogen peroxide solution corresponding to the temperature in the sterilization chamber during sterilization.

36. A process according to claim 34, wherein the removal of the condensate layer takes place at a pressure below the steam pressure of pure hydrogen peroxide at the temperature in the sterilization chamber during sterilization.

37. A process according to claim 32, wherein during a repeat of the pre-evacuation, vapor mix application and re-evacuation steps, the removal of the condensate layer takes place by evacuation of the sterilization chamber to a pressure level below a steam pressure of water corresponding to a temperature in the sterilization chamber during sterilization.

38. A process according to claim 36, wherein the removal of the condensate layer takes place at a pressure below the steam pressure of a water and hydrogen peroxide solution corresponding to the temperature in the sterilization chamber during sterilization.



39. A process according to claim 37, wherein the removal of the condensate layer takes place at a pressure below the steam pressure of pure hydrogen peroxide at the temperature in the sterilization chamber during sterilization.

40. A process according to claim 1, wherein transport container leakage is detected by analysis of sterilization chamber pressure.

41. A process according to claim 39, wherein transport container leakage is detected during the pre-evacuation step.

42. A process according to claim 39, wherein transport container leakage is detected during the re-evacuation step.

43. A process according to claim 2, wherein transport container leakage is detected by analysis of sterilization chamber pressure.

44. A process according to claim 42, wherein transport container leakage is detected during the pre-evacuation step.

45. A process according to claim 42, wherein transport container leakage is detected during the re-evacuation step.

46. A process according to claim 1, wherein transport container leakage occurring before the transport containers are guided into the sterilization chamber is detected by monitoring the curvature of the cover.

47. A process according to claim 45, wherein transport container leakage occurring during the pre-evacuation step is detected by monitoring the curvature of the cover.

48. A process according to claim 45, wherein transport container leakage occurring during the pre-evacuation step is detected by monitoring the curvature of the cover.

49. A process according to claim 2, wherein transport container leakage occurring before the transport containers are guided into the sterilization chamber is detected by monitoring the curvature of the cover.

50. A process according to claim 48, wherein transport container leakage occurring during the pre-evacuation step is detected by monitoring the curvature of the cover.

51. A process according to claim 48, wherein transport container leakage occurring during the pre-evacuation step is detected by monitoring the curvature of the cover.